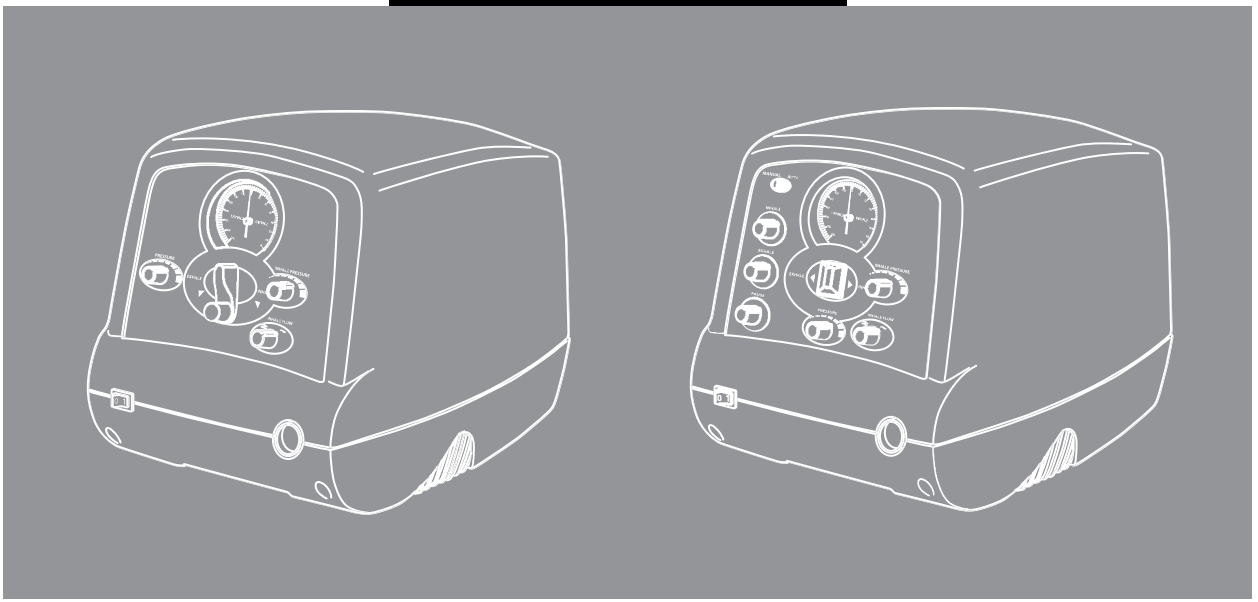
RESPIRONICS®



COUGHASSIST®

USER GUIDE

Table of Contents

Symbol Key

The following symbols appear on this device.

Follow Instructions for Use

Canadian/US Certification

Fuse

AC Power

Type BF Applied Part

Power On

Power Off

Full Inhalation Flow Setting

Reduced Inhalation Flow Setting

Located next to the terminal inside the unit to identify the protective earth connection.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Introduction

Intended Use

For use on any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a face mask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube.

Clinical Settings: For use in a hospital/institutional environment, or in the home, given adequate training and a physician's prescription.

Patient Population: For use on adult or pediatric patients.

Summary

This CoughAssist® Mechanical In-Exsufflator (MI-E) uses a technique referred to as "mechanical insufflation-exsufflation."

- The *automatic* CoughAssist MI-E (Models CA-3000 and CA-3200) has timing mechanisms to automate the inspiratory and expiratory cycles as well as a manual control.

- The *manual* CoughAssist MI-E (Models CM-3000 and CM-3200) uses a manually operated valve to shift from positive to negative pressure and back.

Those who might benefit from the use of the CoughAssist MI-E include any patient with an ineffective cough due to muscular dystrophy, myasthenia gravis, poliomyelitis, or other neurologic disorder with some paralysis of the respiratory muscles, such as spinal cord injury. It may also be used to treat ineffective cough due to other bronchopulmonary diseases, such as emphysema, cystic fibrosis and bronchiectasis. It is effective for both trached and non-invasively ventilated patients.

Contraindications

Any patient with a history of bullous emphysema, known susceptibility to pneumothorax or pnuemo-mediastinum, or known to have had any recent barotrauma, should be carefully considered before use.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

WARNINGS

A warning indicates the possibility for injury to the user or the operator.

- Always check time and pressure settings before each treatment.
- Always use a new filter when using the device on a new patient.
- Patients known to have cardiac instability should be monitored for pulse and oxygen saturation very closely.
- Soreness and/or pain in the chest from a pulled muscle may occur in patients using the CoughAssist MI-E for the first time if the positive pressure used exceeds pressures, which the patient normally receives during Positive Pressure Therapy. Such patients should start at a lower positive pressure during treatment, and gradually (over several days, or as tolerated) increase the positive pressure used. [Positive Pressure Therapy includes the use of a volume ventilator, nasal or mask ventilation or CPAP (Continuous Positive Airway Pressure), or IPPB (Intermittent Positive Pressure Breathing).]
- Do not use in the presence of flammable anesthetics.
- AC power connection should be made to a properly grounded AC outlet only.
- Do not place or store the device where it can fall or be pulled into a tub or sink.
- If the device comes into contact with water, unplug the unit.
- Never operate the CoughAssist MI-E if it has a damaged cord or plug, is not working properly, or has been dropped, damaged or immersed in water.
- Replace fuses only with ones having the same ratings for blow characteristics, current and voltage.
- Do not remove the cover; there are no serviceable parts inside the unit. Refer all service to authorized personnel.
- Use only power cords supplied by Respironics for this device. Use of power cords not supplied by Respironics may cause overheating or damage to the device.

Cautions

A caution indicates the possibility of damage to the device.

- Position the CoughAssist MI-E so that the air intake ports on the side and rear of the unit are not blocked.
- Never operate the device unless a bacterial/viral filter is attached to the patient circuit.
- This device is designed for Intermittent Operation Only and not for continuous use. The device should not be cycled continuously for more than 5 minutes. After such time, the unit should either be turned off or left idling with the blower on for at least 5 minutes.
- Turn the unit off when not in use.
- Keep the power cord away from heated surfaces.
- Do not sterilize with ethylene oxide gas or steam sterilize the pump or pump housing.
- This device should only be used by trained personnel.
- Use only power cords supplied by Respironics with the device. Use of power cords not supplied by Respironics may cause overheating or may damage the device.

How to Contact Respironics

If you need to contact Respironics directly, call the Respironics Customer Service department at 1-800-345-6443 (U.S. and Canada only) or 1-724-387-4000. You can also use the following address:

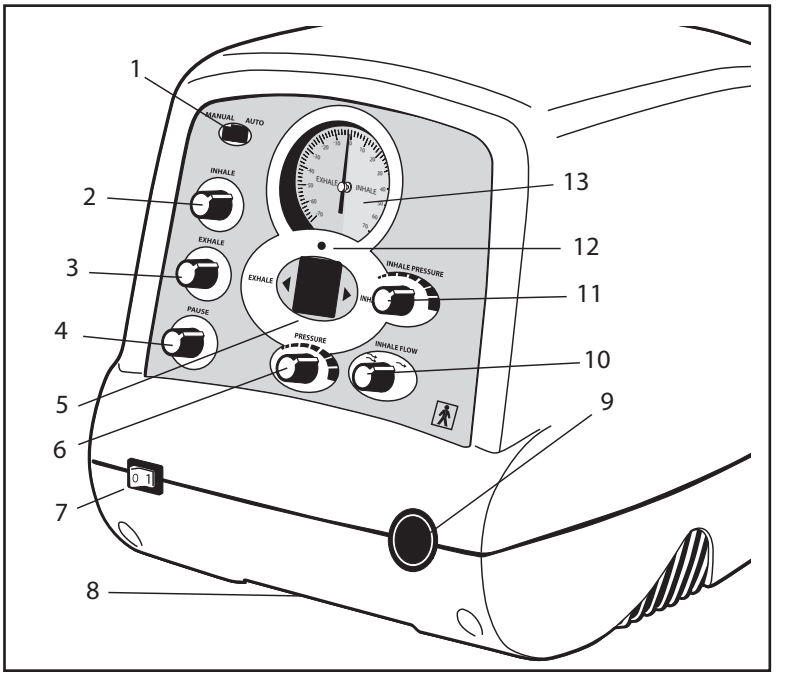
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

Visit the Respironics web site at: www.respironics.com

Controls, Connectors, Visual Indicators

CA-3000, CA-3200 - Automatic Model Front Panel Controls

The items numbered in the illustration below are explained on the next page.

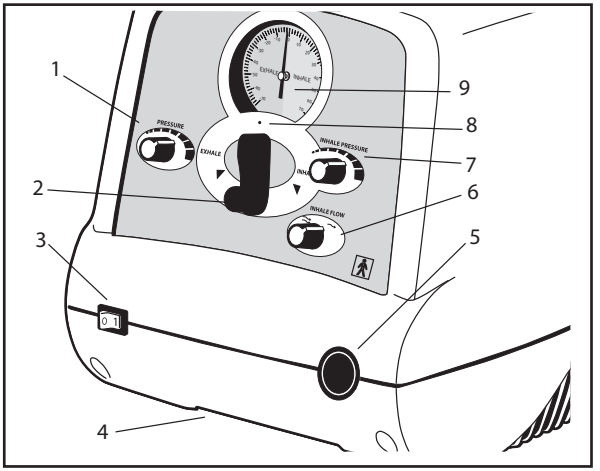


Automatic Model, Front Panel

Item	Symbol or Word	Purpose	Description
1	MANUAL	Manual Mode	Changes the cycling mechanism to manual mode.
	AUTO	Automatic Mode	Changes the cycling mechanism to automatic mode.
2	INHALE	Inhale Phase	Sets time interval (in seconds) for Inhale phase of automatic cycling. Not operative in the manual mode.
3	EXHALE	Exhale Phase	Sets time interval (in seconds) for Exhale phase of automatic cycling. Not operative in the manual mode.
4	PAUSE	Pause Phase	Sets time interval (in seconds) for Pause phase of automatic cycling. Not operative in the manual mode.
5	--	Manual Control Lever	Use to manually cycle the unit to inhale or exhale. Not operative in the automatic mode.
6	PRESSURE	Pressure	Varies the inhalation and exhalation pressures together (also see *Inhale Pressure* below).
7	O	Off Switch	Designates the OFF position.
	I	On Switch	Designates the ON position. When the device is turned on, the green switch light illuminates.
8	--	Handle	Recessed carrying handle.
9	--	Patient Port	Connection for the patient circuit.
10	INHALE FLOW 	Full Setting	Full Inhalation Flow Setting.
	INHALE FLOW 	Reduced Setting	Reduced Inhalation Flow Setting. *NOTE: When using this setting, there will be a small reduction in inspiratory pressure.*
11	INHALE PRESSURE	Inhalation Pressure	Varies the inhalation pressure between 50% and 100% of the exhale pressure (in cm H_2O).
12	--	Set Zero Adjust	Use this "zero" adjustment only if the pressure gauge does not return to "0" when the unit is turned off. (For more information, see the *Troubleshooting* portion of this guide.)
13	--	Pressure Gauge	Indicates the inhalation or exhalation pressure in the patient circuit (calibrated in cm H_2O).

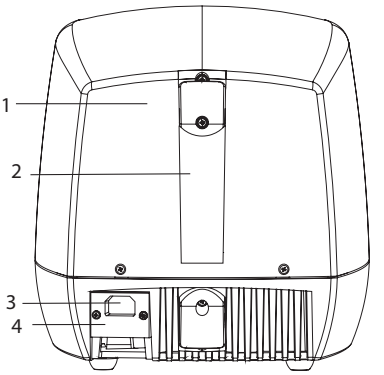
CM-3000, CM-3200 - Manual Model Front Panel Controls

Item	Symbol or Word	Purpose	Description
1	PRESSURE	Pressure:	Varies the inhalation and exhalation pressures together (also see *Inhale Pressure* below).
2	EXHALE	Exhale Phase	Control Lever used to manually cycle the unit to inhale or exhale.
	INHALE	Inhale Phase	
3	O	Off Switch	Designates the OFF position.
	I	On Switch	Designates the ON position. When the device is turned on, the green switch light illuminates.
4	--	Handle	Recessed carrying handle.
5	--	Patient Port	Connection for the patient circuit.
6	INHALE FLOW ≋	Full Setting	Full Inhalation Flow Setting.
	INHALE FLOW ≈	Reduced Setting	Reduced Inhalation Flow Setting. *NOTE: When using this setting, there will be a small reduction in inspiratory pressure.*
7	INHALE PRESSURE	Inhalation Pressure	Varies the inhalation pressure between 50% and 100% of the exhale pressure (in cm H_2O).
8	--	Set Zero Adjust	Use this "zero" adjustment only if the pressure gauge does not return to "0" when the unit is turned off. (For more information, see the *Troubleshooting* portion of this guide.)
9	--	Pressure Gauge	Indicates the inhalation or exhalation pressure in the patient circuit (calibrated in cm H_2O).



Manual Model, Front Panel

Back Panel Controls (All Models)



1. Cord Wrap/Breathing Hose Holder
2. Warning label with fuse information shown below.
3. Power Cord Receptacle:
   Securely connects the power cord to the receptacle.
4. Replacement fuse location

Replacement Fuses

Follow the detailed steps on page 18 to replace the fuses.

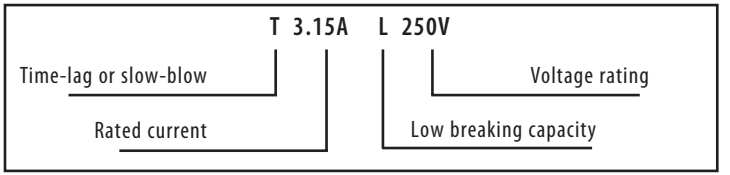
The fuse for your CoughAssist is either 3.15 amp or 3.0 amp. To determine the correct replacement fuse for your device, refer to the label on the back of the unit.

3.15 Amp Unit

If your unit requires a 3.15 amp fuse, the labels says **T 3.15A** L250V. Replacement fuses must have the following characteristics:

Sample Label

Replacement Fuse Characteristics

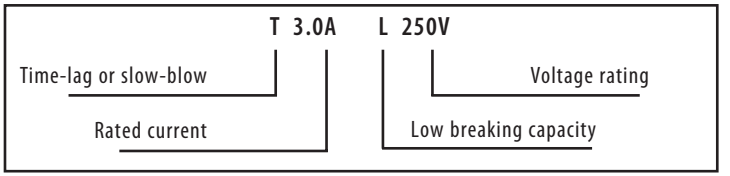


3.0 Amp Unit

If your unit requires a 3.0 amp fuse, the labels says **T 3.0A** L250V. Replacement fuses must have the following characteristics:

Sample Label

Replacement Fuse Characteristics

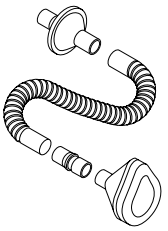


Accessories

The following replacement accessories may be obtained from Respironics. For additional accessories visit www.respironics.com or http://coughassist.respironics.com

CoughAssist MI-E Patient Circuit
(Part No. 325-9217)

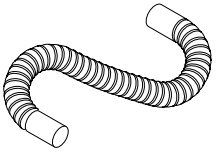
The CoughAssist MI-E Patient Circuit consists of one 3-ft (1 m) long flexible smooth bore tube, a bacterial/viral filter, an adult face mask and an adapter.



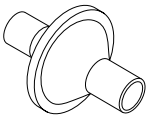
Breathing Hose (Part No. 732-1136)

3-ft (1 m) long flexible smooth bore tubing with 22 mm interior diameter.

NOTE: Corrugated tubing may cause a small reduction in flow rates as well as cause a whistling sound. The use of tubing greater than 3-ft (1 m) in length may cause a small reduction in flow rates as well.

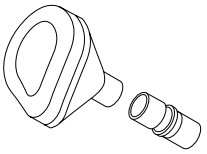


Bacterial/Viral Filter (Part No. 740-1006)



Face mask (Part No. 740-1007)
and Adapter (Part No. 740-1008)

(Each with 22 mm outside diameter)

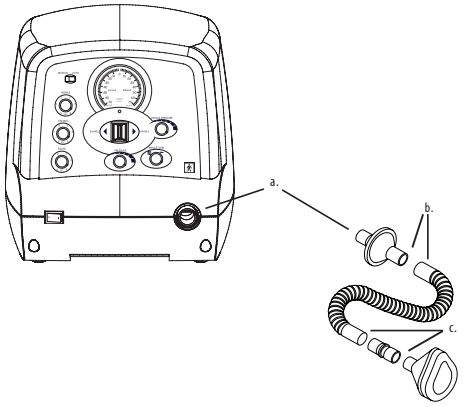


INITIAL SET-UP

1. Install the power cord right angle connector to the receptacle on the rear of the device. Run the cord inside of the lower cord wrap to act as a strain relief.

2. Position the unit on a suitable surface within easy reach of the patient, or the operator of the unit. CAUTION: Position the device so that the air intake ports on the side and rear of the unit are not blocked.

3. Assemble the patient circuit (filter, breathing hose and patient interface) as shown here on the automatic model.



AUTOMATIC MODEL SHOWN HERE

   a. Attach the bacterial/viral filter to the patient port on the front panel.

   b. Attach the smooth bore breathing hose [3-ft (1 m) x 22 mm ID] to the bacterial/viral filter.

   c. Attach the appropriate patient interface to the breathing hose. Patient interface options include a face mask and adapter, mouthpiece, lip seal or tracheostomy tube adapter. (A face mask and adapter are included with each unit.)

4. Plug the power cord into a properly grounded AC outlet of appropriate voltage.

Daily Use

CAUTION: This unit is designed for Intermittent Operation Only and not for continuous use. The device should not be cycled continuously for more than 5 minutes. After such time, the unit should either be turned off or left idling with the blower on for at least 5 minutes.

Manual Operation (All Models)

1. Attach the appropriate patient interface to the patient.

2. On automatic models only, shift manual/auto switch to the manual position.

3. Shift the manual control lever to the inhale position (to the right) and observe the pressure gauge to see the pressure build slowly over 2 to 3 seconds.

4. Rapidly shift the manual control lever to the exhale position (to the left) to induce the cough, holding it there for 1 to 2 seconds.

5. Leave the lever in the neutral position for a few seconds or shift it immediately to the positive pressure phase for another cough cycle, depending on the patient's preference.

6. After 4 to 5 cycles, remove the patient interface from the patient and allow time for a normal breathing pattern to return (20 to 30 seconds), or place the patient back on the ventilator if currently in use. Avoid prolonged periods connected to the device. During this resting period, clear secretions that may have become visible in the mouth, throat or tracheostomy tube.

Automatic Operation (Automatic Models Only)

1. Attach the appropriate interface to the patient.

2. Set the manual/auto switch to the auto position. The unit will cycle from inhale (positive) to exhale (negative) to zero pressure, and back to positive.

3. After 4 to 5 cycles, set the manual/auto switch back to the manual position. Remove the patient interface from the patient and allow time for a normal breathing pattern to return (20 to 30 seconds), or place the patient back on the ventilator if currently in use. Avoid prolonged periods connected to the device. During this resting period, clear secretions that may have become visible in the mouth, throat or tracheostomy tube.

Treatment

WARNING: Always check the time and pressure settings before each treatment.

Treatment usually consists of 4 or 5 coughing cycles in succession. The patient is then allowed to rest for 20 to 30 seconds, which helps avoid hyperventilation. The cycles can then be repeated 4 to 6 times for a full treatment.

Operation Verification (All Models)

It is recommended that the CoughAssist MI-E be periodically tested to ensure that the cycling valve returns to the neutral, the pause, position after either the inhale or exhale phase. To determine this, follow these steps:

1. Attach a patient circuit to the unit and block the end of the hose.

2. Turn the power switch ON.

3. For automatic models only, set the manual/auto switch to the manual position.

4. Set the pressure knob to maximum pressure (fully clockwise).

5. Cycle the manual control lever from inhale to exhale and observe the pressure gauge to ensure that positive and negative pressure is being applied to the patient circuit.

6. Release the manual control lever from the inhale position and observe that the pressure immediately drops to 0 cm H_2O. Repeat for the exhale position. In either case, if the pressure does not drop to zero, the unit should be returned for repair.

Pressure Adjustment

Each patient may require special settings for the maximum positive (inhalation) and negative (exhalation) pressures. For a patient using this device for the first time, it is advisable to begin with lower pressures, such as 10-15 cm H_2O positive and negative, to familiarize the patient with the feel of mechanical insufflation-exsufflation. During subsequent treatments, pressures can be increased as necessary to achieve adequate secretion clearance. See the Warnings section of this guide.

Note that at these lower pressures the device may have limited effectiveness in clearing secretions. Increasing pressures should improve the effectiveness.

1. Turn on the power switch.

2. Set the inhale flow to full or reduced.

3. Attach the patient circuit to the unit and block the end of the breathing hose.

4. Set the manual/auto switch to manual (automatic models only).

5. Push the manual control lever to the exhalation phase (to the left). Observe the pressure gauge on the device and adjust the maximum pressure (negative) using the pressure knob to achieve the correct reading on the gauge.

6. Shift the manual control lever to the inhalation phase (push to the right). Adjust the pressure reading by turning the inhale pressure knob to achieve the correct reading on the pressure gauge (clockwise to increase pressure and counterclockwise to decrease pressure).

7. Cycle the manual control lever from inhale (positive) to exhale (negative) and back a few times to ensure that the pressure and suction readings are correct.

8. Release the manual control lever to ensure that the pressure immediately returns to 0 cm H_2O. If the pressure does not drop to zero, the unit should be returned for repair.

Timing Adjustment (Automatic Models Only)

If the device's automatic feature is to be used, adjust the times as follows:

1. Each cough cycle consists of an inhalation phase, an exhalation phase and a pause phase, after which inhalation begins again. The time for each phase is set with the three knobs on the left side of the front panel. Normally, inhale time and exhale time are set to 1 to 3 seconds and the pause time can be set up to 5 seconds, or eliminated by setting the pause time knob to 0 seconds, depending on the patient's preference.

2. Set the manual/auto switch to the auto position and observe that the unit cycles from positive to negative pressure, then to zero pressure, and repeats until the switch is set back to manual. When set to the manual position, the unit should return to 0 cm H_2O. If the pressure does not drop to zero, the unit should be returned for repair.

Preventive Maintenance

This device has been designed to provide virtually maintenance-free operation for extended periods of time. Sharp blows to the unit or dropping the unit are to be avoided. No routine maintenance is required.

1. Keep the unit's exterior clean.

2. Check that the air intake ports are not blocked.

3. Keep the device away from curtains, blankets or any heat generating device.

WARNING: *Do not remove the cover. There are no serviceable parts inside the unit. Refer all service to authorized personnel.*

TECHNICAL INFORMATION: Respironics will make available on request a list of all repairable exterior parts with descriptions. Interior schematics and circuit diagrams will be made available to qualified technical personnel only.

Cleaning

External Housing

The exterior of the device may be washed with a mild detergent and water, or with a bactericidal cleaning solution such as 70% isopropyl alcohol.

CAUTION: Do not sterilize the device with ethylene oxide gas or steam.

Patient Circuit

WARNING: Do not attempt to sterilize the patient circuit. Always use a new filter when using the device on a new patient.

Institutional (Hospital) Use

- Breathing Circuit: Breathing Hose, Patient Interface and Adapters:
  If the device is to be used by more than one patient, the circuit must be replaced.

- Bacterial/Viral Filter:
  If the device is to be used by more than one patient, the filter must be replaced to prevent cross contamination. Do not try to wash the filter.

Home (Individual) Use

- Breathing Hose, Patient Interface and Adapters:
  After use, the breathing hose and patient interface should be washed thoroughly in liquid dishwashing soap and water. These parts must completely air dry before reuse.

- Bacterial/Viral Filter:
  The filter, which protects the device from entraining foreign material from the patient, can be left in place as long as it is not blocked by sputum or trapped moisture. Do not try to wash the filter.

Troubleshooting Guide

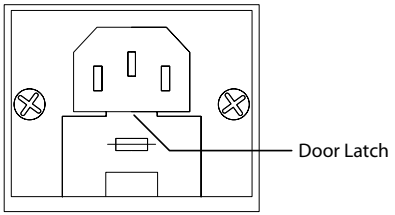
1. Pressure Gauge Adjustment: If the pressure gauge does not return to zero when the device is turned off, it must be readjusted. Remove the adhesive cover over the pressure gauge zero adjust and turn the adjustment screw to "0" using a screwdriver. If you are unable to make this adjustment, the unit should be returned for servicing.

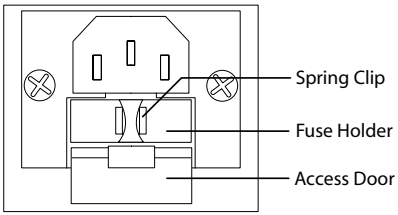
2. Fuse Replacement: If the unit is connected to the proper power source and the green light within the power switch does not illuminate when the switch is actuated, one or both of the two safety fuses may have blown. The procedure for replacement of a blown fuse is below.

   Warning: be sure to replace the fuse with an identical one, as described on page 9.

   a. Disconnect the unit from any power outlet and disconnect the power cord from the receptacle on the rear of the unit (see the Back Panel diagram on page 9).

   b. Locate the access door on the receptacle labeled with the fuse symbol:  . Open the access door by prying the latch at the top with a small screwdriver or fingernail. Pivot the door down to reveal the two fuse holders.





   c. Press each of the two spring clips to the side. (Push the left one to the left and the right one to the right.)

   d. Slide both fuse holders out of the receptacle.

   e. Inspect both fuses and replace them, if necessary, with fuses with equivalent ratings, as described on page 9. To replace a fuse, slide a new fuse into its place.

   f. Make sure each fuse and holder is placed back into the receptacle.

   g. Close the access door and reconnect the power cord.

Specifications

Dimensions:	11.5 x 11 x 16.5 in. (29.2 x 27.9 x 41.9 cm)
Weight:	CA-3000, CA-3200: 24 lbs. (11 kg.) CM-3000, CM-3200: 20.6 lbs. (9.3 kg.)

	Operation	Transport & Storage
Temperature:	50° to 104° F (10° to 40° C)	-4° to 122° F (-20° to 50° C)
Humidity:	30 to 75%, noncondensing	15 to 90%, noncondensing

Positive Pressure:	Can be set from 5 to 60 cm H_2O for both automatic and manual
Negative Pressure:	Can be set from 5 to 60 cm H_2O for both automatic and manual
Standards:	Conforms to UL STD 2601-1, certified to CAN/CSA STD C22.2 No. 601.1-M90
Typical Inhalation Flow:	3.3 liters/second with inhale flow set to minimum; if set to maximum inhalation, the flow is the same as the exhalation flow
Typical Exhalation Flow Capacity:	10 liters/second. Actual flow depends upon set pressure and on patient airway resistance.
Pressure Gauge:	-70 to 0 to +70 cm H_2O; accuracy ± 6 cm H_2O
Mode of Operation:	CA-3000, CA-3200: Both automatic and manual timing CM-3000, CM-3200: Manual timing only
Inhalation, Exhalation, Pause Times:	CA-3000, CA-3200: Automatic mode, 0 to 5 seconds CM-3000, CM-3200: User variable
"Off" Position:	Yes - connects to ambient
Blower Type:	Two-stage centrifugal blower with AC/DC universal motor
Input Voltage:	CA-3000, CM-3000: 110-120 VAC, 60Hz CA-3200, CM-3200: 220-240 VAC, 50Hz
Input Power:	CA-3000, CM-3000: 300 VA, CA-3200, CM-3200: 600 VA

Equipment Classification

Per IEC 60601-1, Medical Electrical Equipment, General Requirements for Safety, the device is classified as follows:

- Class I Equipment
- Type BF Applied Part
- IPX0: Ordinary protection against ingress of liquid.

This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.

This device is designed for Intermittent Operation Only and not for continuous use. The device should not be cycled continuously for more than 5 minutes. After such time, the unit should either be turned off or left idling with the blower on for at least 5 minutes.

Disposal

Dispose of the device in accordance with local regulations.

EMC Information

CAUTIONS

- Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents (see below).
- Portable and mobile RF Communications Equipment can affect Medical Electrical Equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions: The device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The CoughAssist uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CoughAssist is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

WARNING

The equipment or system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions: The device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 sec	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CoughAssist requires continued operation during power mains interruptions, it is recommended that the CoughAssist be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity: The device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m[1] 80 MHz to 2.5 GHz	1 V/m	$d = 3.5 \sqrt{P}$ 80 MHz to 800 MHz $d = 7.0 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey **a**, should be less than the compliance level in each frequency range **b**. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3: The technology used to regulate pressure in the CoughAssist could not be modified with reasonable effort to provide immunity at a 3 V/m level. As a result all user guidance has been provided for a 1 V/m field level at which the system was found immune.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b: Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device:
The CoughAssist is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the CoughAssist can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the CoughAssist as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.1667 \sqrt{P}$	80 MHz to 800 MHz $d = 3.5 \sqrt{P}$	800 MHz to 2.5 GHz $d = 7 \sqrt{P}$
0.01	0.11667	0.35	0.7
0.1	0.36894	1.107	2.214
1	1.1667	3.5	7.0
10	3.6894	11.07	22.14
100	11.667	35	70

Limited Warranty

Respironics, Inc. ("Respironics") warrants that for a period of one (1) year from the date of sale by Respironics to the dealer, the CoughAssist MI-E system shall be free from defects in materials and workmanship and will perform in accordance with the product specifications. CoughAssist MI-E system accessories purchased from Respironics are warranted to be free of defects in materials and workmanship for a period of 90 days from the date of purchase. If the CoughAssist MI-E system or a CoughAssist MI-E system accessory fails to perform in accordance with its specifications during the warranty period, Respironics will repair or replace – at Respironics' option – the defective unit or accessory. Respironics will pay customary freight charges from Respironics to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

THE WARRANTIES SET FORTH ABOVE ARE GIVEN IN LIEU OF ALL OTHER EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THE COUGHASSIST MI-E SYSTEM AND ITS ACCESSORIES. RESPIRONICS DOES NOT MAKE, AND HEREBY SPECIFICALLY DISCLAIMS, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL RESPIRONICS BE LIABLE FOR, AND RESPIRONICS HEREBY SPECIFICALLY DISCLAIMS, ALL LIABILITY FOR ECONOMIC LOSS, LOST PROFITS, LOSS OF GOOD WILL, OR INCIDENTAL OR CONSEQUENTIAL DAMAGES, ARISING FROM USE OR SALE OF THE COUGHASSIST MI-E SYSTEM AND ITS ACCESSORIES EVEN IF RESPIRONICS HAS BEEN ADVISED OF THE POSSIBILITY OF THE SAME.

SOME STATES OR PROVINCES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF IMPLIED WARRANTIES OR THE DISCLAIMER OF INCIDENTAL AND CONSEQUENTIAL DAMAGES. ACCORDINGLY, THE LAWS OF YOUR STATE OR PROVINCE MAY GIVE YOU ADDITIONAL PROTECTIONS.

To exercise your rights under this warranty, contact your local authorized Respironics dealer. You may also visit the Respironics home page on the web at www.respironics.com.

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